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ATTORNEY FOR APPLICANT

March 11, 2002
DATE OF SIGNATURE

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In the Application of: Dr. Donald G. Russell)
) Group Art Unit: 2882
on)
AN INTERMEDIATE DENSITY MARKER AND A METHOD USING SUCH A MARKER FOR RADIOGRAPHIC EXAMINATION) Examiner: C. E. Church
Application Serial No. 09/372,835)
Filed on August 12, 1999) (Docket No. 054360.0005)

Dated at Hartford, Connecticut, this 11th day of March 2002.

Commissioner for Patents
Washington, DC 20231

APPELLANT'S APPEAL BRIEF

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I. INTRODUCTION

In accordance with the provisions of 35 U.S.C. § 134 and 37 C.F.R. §§ 1.191 and 1.192, this Appeal Brief is submitted in triplicate in support of the appeal from the Office action dated August 12, 1999, finally rejecting claims 20-61.

A. Real Party In Interest

Appellant has assigned his interest in the subject application to Beekley Corporation.

B. Related Appeals and Interferences

None.

II. STATUS OF THE CLAIMS

A. Status of Pending Claims

Claims 20-61 are pending in this application. Claims 20-61 have been finally rejected under 35 U.S.C. § 103 and each of these claims are on appeal.

B. Status of Canceled Claims

The subject application, U.S. Patent Application Serial No. 09/372,835, was filed on August 12, 1999, as a continuation of U.S. Patent Application Serial No. 08/934,121. The subject application was filed with nineteen (19) claims.

In a Preliminary Amendment, dated October 10, 2000, original claims 1-19 were canceled, without prejudice, and new claims 20-53 were added. In an Amendment dated April 23, 2001, claims 54-61 were added. Thus, the following claims have been

canceled, without prejudice, during prosecution of the subject application and are not on appeal herein: Claims 1-19.

III. STATUS OF THE AMENDMENTS

There were no amendments filed subsequent to the final rejection of this application. Appellant filed a Response To Office Action (Final Rejection) under 37 C.F.R. § 1.116 on November 29, 2000, offering arguments to surmount the rejection. An Advisory Action was then issued stating that the arguments contained in the response failed to overcome the rejections.

IV. SUMMARY OF THE INVENTION

Appellant's claimed invention is directed to an intermediate density marker and a method using such a marker for radiographic examination. The marker of the invention is for mammographic examination of breast tissue having anatomical detail present in the tissue, wherein a source of x-ray radiation is provided for generating radiation at a predetermined energy level suitable for imaging the breast tissue. The marker is positioned between the source of x-ray radiation and the breast tissue and the marker and breast tissue are exposed to the x-ray radiation at a predetermined energy level to generate a radiographic image of the tissue having the shadow of the marker superimposed thereon. The marker is comprised of:

1. a first outer surface for contacting a patient's breast tissue;
2. a second outer surface located on an opposite side of the marker relative to the first outer surface; and

3. means located between the first and second outer surfaces for generating a radiographic image of the tissue having the shadow of the marker superimposed thereon with the anatomical detail present in the tissue clearly visible through the radiographic shadow projected by the marker.

The method of the present invention is also directed to radiographic examination of tissue having anatomical detail present in the tissue. The method includes the following steps:

1. providing a source of x-ray radiation having a predetermined energy level capable of generating radiation suitable for imaging a predetermined tissue density;

2. providing a partially radiolucent, partially radiopaque marker having a radiographic density and thickness which permit the marker to both project a radiographic shadow and transmit sufficient radiation to image anatomical detail present in tissue having the predetermined tissue density when the marker and the tissue are exposed to the predetermined level of x-ray radiation during radiographic examination;

3. selecting the density and thickness of the marker based on the predetermined tissue density and the predetermined energy level of the radiation provided to absorb from about 2% to about 75% of the incident radiation;

4. positioning of the marker between the source of x-ray radiation and the tissue having the predetermined tissue density; and

5. exposing the marker and the tissue to the x-ray radiation at the predetermined energy level and generating a radiographic image of the tissue having the shadow of the marker superimposed thereon with the anatomical detail present in the tissue clearly visible through the radiographic shadow projected by the marker.

V. ISSUES

The issues raised in the Final Rejection requiring resolution in this Appeal are as follows:

A. Whether claims 20-61 are properly rejected under 35 U.S.C. § 103 as being unpatentable over Zinreich et. al. (U.S. Patent No. 5,469,847).

B. Whether claims 20-61 are properly rejected under 35 U.S.C. § 103 as being unpatentable over Desena (U. S. Patent No. 5,193,106).

VI. GROUPING OF CLAIMS

The claims on appeal before the Board of Patent Appeals and Interferences are claims 20-61. All of claims 20-61 relate to an intermediate density marker and a method of using such a marker for radiographic examination.

The claims on appeal are set forth in the Appendix, and the independent claims 20, 36, 46, 55, and 59 are set forth below:

20. A method of radiographic examination of tissue having anatomical detail present in the tissue, comprising the steps of:

providing a source of x-ray radiation capable of generating radiation suitable for imaging the tissue;

selecting a partially radiolucent, partially radiopaque marker having a radiographic density and thickness which permit the marker to both project a radiographic shadow and transmit sufficient radiation to image anatomical detail present in the tissue when the marker and the tissue are exposed to the x-ray radiation during radiographic examination, wherein the marker comprises at least one of aluminum, rubber, plastic and vinyl, the thickness of the marker is less than about 0.4 inches, and the thickness of the marker is selected based upon the density of the tissue being examined and the energy of the radiation being applied to absorb from about 2% to about 75% of the incident radiation;

positioning the marker between the source of x-ray radiation and the tissue; and

exposing the marker and the tissue to the x-ray radiation, and generating a radiographic image of the tissue having the shadow of the marker superimposed thereon with the anatomical detail present in the tissue clearly visible through the radiographic shadow projected by the marker.

36. A method of radiographic examination of tissue having anatomical detail present in the tissue, comprising the steps of:

providing a source of x-ray radiation having a predetermined energy level capable of generating radiation suitable for imaging a predetermined tissue density;

providing a partially radiolucent, partially radiopaque marker having a radiographic density and thickness which permit the marker to both project a radiographic shadow and transmit sufficient radiation to image anatomical detail present in tissue having the predetermined tissue density when the marker and the tissue are exposed

to the predetermined level of x-ray radiation during radiographic examination, said providing step including selecting the density and thickness of the marker based on the predetermined tissue density and the predetermined energy level of the radiation provided to absorb from about 2% to about 75% of the incident radiation;

positioning the marker between the source of x-ray radiation and the tissue having the predetermined tissue density; and

exposing the marker and the tissue to the x-ray radiation at the predetermined energy level, and generating a radiographic image of the tissue having the shadow of the marker superimposed thereon with the anatomical detail present in the tissue clearly visible through the radiographic shadow projected by the marker.

46. A marker for radiographic examination of tissue having anatomical detail present in the tissue, wherein a source of x-ray radiation is provided for generating radiation at a predetermined energy level suitable for imaging tissue having a predetermined tissue density, the marker is positioned between the source of x-ray radiation and the tissue, and the marker and tissue type are exposed to the x-ray radiation at the predetermined energy level to generate a radiographic image of the tissue having the shadow of the marker superimposed thereon, the marker comprising:

a first outer surface for contacting a patient's skin; a second outer surface located on an opposite side of the marker relative to the first outer surface; and at least one partially radiolucent, partially radiopaque material located therebetween, said at least one partially radiolucent, partially radiopaque material defining a density and thickness based on the predetermined tissue density and the predetermined energy

level of the radiation provided which absorbs from about 2% to about 75% of the incident radiation and, in turn, generates a radiographic image of the tissue having the shadow of the marker superimposed thereon with the anatomical detail present in the tissue clearly visible through the radiographic shadow projected by the marker.

55. A marker for mammographic examination of breast tissue having anatomical detail present in the tissue, wherein a source of x-ray radiation is provided for generating radiation at a predetermined energy level suitable for imaging breast tissue, the marker is positioned between the source of x-ray radiation and the breast tissue, and the marker and breast tissue are exposed to the x-ray radiation at the predetermined energy level to generate a radiographic image of the tissue having the shadow of the marker superimposed thereon, the marker comprising:

a first outer surface for contacting a patient's breast tissue; a second outer surface located on an opposite side of the marker relative to the first outer surface; and means located between the first and second outer surfaces for generating a radiographic image of the tissue having the shadow of the marker superimposed thereon with the anatomical detail present in the tissue clearly visible through the radiographic shadow projected by the marker.

59. A method of mammographic examination of breast tissue having anatomical detail present in the tissue, comprising the steps of:

providing a source of x-ray radiation having a predetermined energy level capable of generating radiation suitable for imaging breast tissue;

providing a partially radiolucent, partially radiopaque marker having a radiographic density and thickness which permit the marker to both project a radiographic shadow and transmit sufficient radiation to image anatomical detail present in breast tissue when the marker and the tissue are exposed to the predetermined level of x-ray radiation during mammographic examination;

positioning the marker between the source of x-ray radiation and the breast tissue; and

exposing the marker and the tissue to the x-ray radiation at the predetermined energy level, and generating a radiographic image of the tissue having the shadow of the marker superimposed thereon with the anatomical detail present in the tissue clearly visible through the radiographic shadow projected by the marker.

Pursuant to 37 C.F.R. § 1.192(c)(7), Appellant hereby groups the pending claims for purposes of appeal as follows:

Claims 20-61 stand rejected under 35 U.S.C. § 103 over Zinreich et. al.	Rejected claims stand or fall together
Claims 20-61 stand rejected under 35 U.S.C. § 103 over Desena	Rejected claims stand or fall together

VII. ARGUMENT

Claims 20-61 stand rejected under 35 U.S.C. § 103 as being unpatentable over U.S. Patent No. 5,469,847 to Zinreich et al., and in the alternative, stand rejected under 35 U.S.C. § 103 as being unpatentable over U.S. Patent No. 5,193,106 to DeSena. The Examiner's grounds for rejection are hereinafter traversed, and allowance respectfully requested, in view of the arguments below and evidence of non-obviousness of the claimed invention through commercial success documented in the previously submitted Declaration of Denise Zielanski.

A. Zinreich et al. Do Not Teach Or Suggest The Claimed Invention.

Zinreich et al. do not teach or suggest providing a marker made of a partially radiopaque, partially radiolucent material, and generating a radiographic image of the tissue having the shadow of the marker superimposed thereon with the anatomical detail of the tissue clearly visible through the radiographic shadow of the marker, as recited in the independent claims.

To the contrary, Zinreich et al. teach a multi-modality marker, i.e., one that can be used with multiple imaging methods, such as x-ray, CT, ultrasound, PET, MRI and others. (See col. 3, lines 5-11). For x-ray applications, Zinreich et al. specifically teach the use of radiopaque materials. More specifically, Zinreich et al. state that the gel 12 "is sufficiently *X-Ray-opaque* for adequate imaging on CT or X-Ray." (Col. 3, line 65 through col. 4, line 1; emphasis added). Zinreich et al. further teach that additional x-ray opaque materials may be used in addition to the radiopaque gel 12. Zinreich et al. specifically state: "an *X-Ray-opaque* metal, metallic powder or particles, or metallic salt

(e.g., barium sulfate) may be laid into the outer casing 20 in addition to the gel 12." (Col., 6, lines 9-15; emphasis added).

Thus, Zinreich et al. in no way teach or suggest employing a partially radiopaque, partially radiolucent material in order to generate a radiographic image of the tissue with the shadow of the marker superimposed thereon, and the anatomical detail present in the tissue clearly visible through the radiographic shadow of the marker, as recited in the independent claims. Rather, it is only through impermissible hindsight reconstruction that one can assert that Zinreich et al. teach these claimed features of the invention. As summarized above, Zinreich et al. specifically teach forming the marker of a radiopaque material, and further teach placing the marker to the side of the tissue to be viewed, and generating either a "heavy, bright" or "heavy, dark" image of the radiopaque marker. Zinreich et al. state: "In images created from either MRI or X-Ray modalities (including CT) a marker 10 appears in side view as a *heavy, bright line* on a negative image or a *heavy, dark line* on a positive image. If the image is taken perpendicular to a top surface 11 of the marker 10, the marker 10 appears as a *bright disk shape* on negative images or as a *dark disk shape* on positive images." (Col. 5, lines 4-9; emphasis added). Thus, contrary to the Examiner's assertion at page 4 of the Action, Zinreich et al. in no way teach or suggest in x-ray applications "markers that are only barely visible and certainly are not entirely opaque so as to obliterate the image". Rather, in x-ray applications, Zinreich et al. clearly teach creating either a "heavy, bright" or "heavy, dark" image, and placing such radiopaque markers to the side of the tissue to be viewed. Clearly, if Zinreich et al.'s x-ray markers were partially radiopaque and partially radiolucent as recited in the present claims, Zinreich et al. would not require that the markers be placed

to one side of the tissue being viewed, nor would Zinreich et al. describe the marker as generating a "heavy, dark line" or "heavy, bright line" image. Zinreich et. al. specifically reference the production of an opaque image whose deficiency is specifically that being addressed by the appellant's invention.

Contrary to the Examiner's assertion, the passage in Zinreich et al. cited at page 4 of the Action does not change this clear teaching away from the present invention. The passage at column 3, lines 6-12 of Zinreich et al. stating that the multi-modality surface marker "does not produce undesirable aberrations which obscure portions of the diagnostic images", is merely referring to the production of "streak artifacts" that occur when CT imaging with some prior art markers. These streak artifacts are those that "produce undesirable aberrations which obscure portions of the diagnostic images... ." This problem is also described, for example, in the "background" portion of the present application at page 2, lines 6-13. This passage is in no way referring to the possibility of radiopaque markers blocking underlying anatomical detail, much less referring to the solution of the claimed invention of providing partially radiopaque, partially radiolucent markers that allow anatomical detail falling within the marker's shadow to be clearly visible on the image, as recited in the independent claims. Moreover, this passage in no way teaches or suggests creating "barely visible" x-ray markers as suggested by the Examiner at page 4 of the Action. Contrary to the Examiner's assertion at page 4 of the Office Action concerning the term "sufficiently" in Zinreich et al., the reference does not teach or suggest in any way varying the radiopacity of the subject markers. Rather, Zinreich et al. is directed entirely toward multi-modality markers that could effectively be used in multiple imaging methods.

It is black letter law that the prior art references must be taken in their entireties, including those portions that weigh against obviousness. Moreover, it is impermissible for the Examiner to pick and choose from a reference only so much of it as might support a conclusion of obviousness to the exclusion of other parts necessary to full appreciation.

In this case, Zinreich et al., when properly viewed in its entirety, teaches radiopaque x-ray markers that produce opaque images on the x-ray obscuring any information on the tissue behind the marker, and in no way teaches or suggests the markers of the claimed invention.

B. DeSena Does Not Teach Or Suggest The Claimed Invention

Like Zinreich et al., DeSena also is directed specifically to radiopaque markers. In each instance, DeSena's markers are described as "radiopaque". DeSena states: "Said marker devices 3 comprise a pressure sensitive adhesive medical tape 1 onto which a flexible *radiopaque* material is affixed." (Col. 4, lines 31-34; emphasis added). Similarly, DeSena describes the markers as "radiopaque" at col. 4, lines 52-54 ("the radiopaque material"), and column 5, lines 7-10 ("said radiopaque material"). Because DeSena's markers are radiopaque they would obscure radiographic detail if placed directly over the area of interest. Accordingly, DeSena further teaches forming the markers in perimeter shapes that "are large enough to *encompass* the region of interest". (Col. 3, lines 65-66; emphasis in original). Clearly, DeSena teaches avoiding the danger of obscuring radiographic detail not by making the marker partially radiolucent, as recited in the present claims, but by placing the radiopaque marker around and outside of the area of interest. (See also col. 5, lines 7-11 and limitation "b" of claim 1 of DeSena).

Thus, to modify the markers disclosed by DeSena in the manner suggested by the Examiner would be contrary to the express teachings of DeSena.

The passage cited by the Examiner at page 4 of the Action in no way suggests creating partially radiopaque, partially radiolucent markers that allow anatomical detail falling within the marker's shadow to be clearly visible on the image, as recited in the independent claims. Nor does this passage otherwise change the clear teaching of DeSena to make the marker radiopaque, as described above. Rather, the cited passage simply explains the manner of making the radiopaque markers. Clearly, in this case, the Examiner is not viewing the DeSena reference in its entirety, but rather is attempting to pick and choose from DeSena only those portions of the reference that -- when taken out of context and viewed with impermissible hindsight -- support an argument of obviousness.

A significant advantage of the present invention is that the image of the partially radiopaque, partially radiolucent marker is superimposed over the image of the tissue with the anatomical detail present in the tissue clearly visible through the radiographic shadow of the marker, as recited in the independent claims. As a result, the marker cannot block the image of any underlying anatomical detail, nor can the image of the marker itself be mistaken for anatomical detail. Zinreich et al. and DeSena show no recognition of these problems, much less teach a solution to these problems as recited in the independent claims.

Although the Examiner asserts that it would have been obvious to adjust the thickness or percentage of attenuation of the markers shown in either Zinreich et al. or DeSena, the Office Action fails to point to any specific teaching in the prior art references

of record suggesting modification of these prior art markers to be partially radiopaque and partially radiolucent, much less any teaching to generate radiographic images of the markers with anatomical detail of the tissue clearly visible through the shadow of the marker, as recited in the independent claims. Rather, it is only through the impermissible application of hindsight that one can assert that either Zinreich et al. or DeSena teach or suggest these claimed features of the invention.

C. The Commercial Success Of The Present Invention Dictates A Conclusion Of Non-Obviousness

Evidence of secondary considerations of non-obviousness, including commercial success, "may often be the most probative and cogent evidence in the record. It may often establish that an invention appearing to have been obvious in light of the prior art was not." Ruiz v. A.B. Chance Company, 2000 WL 17832367 (Fed. Cir. Dec. 6, 2000). Accordingly, the PTO must give secondary considerations -- including commercial success -- due weight in all cases where presented. In re Sernaker, 702 F.2d 989 (Fed. Cir. 1983). It is respectfully submitted that the Examiner's apparent refusal to consider such evidence in this case is error, and that such evidence clearly dictates a finding of non-obviousness of the claimed invention.

As set forth in the Declaration of Denise Zielanski, an employee of the assignee of the present invention, Beekley Corp., the markers embodying the invention have enjoyed significant commercial success directly attributable to the claimed features of the invention. Accordingly, this evidence indisputably shows both the commercial success of the claimed invention, and the non-obviousness of the claimed invention over the prior art references cited by the Examiner.

As set forth in the Zielanski Declaration, the Beekley markers embodying the claimed invention are referred to by Beekley as "Light Image" markers because they are made of a partially radiolucent, partially radiopaque material that generates a radiographic image of the tissue having the shadow of the marker superimposed thereon, with the anatomical detail present in the tissue clearly visible through the radiographic shadow projected by the marker, as recited in the independent claims of this application. (Zielanski Declaration at ¶ 2).

Beekley began selling the Light Image markers in 1996, and since then has sold the following three types of Light Image markers: Beekley's A-SPOTS® markers used for marking palpable masses (Exhibit A to the Zielanski Declaration), Beekley's O-SPOTS® markers used for marking moles (Exhibit B to the Zielanski Declaration), and Beekley's S-SPOTS® markers used for marking scars (Exhibit C to the Zielanski Declaration). As can be seen in the Exhibits to the Zielanski Declaration, Beekley's commercial products constitute the invention disclosed and claimed in this application (as opposed, for example, to being only a component of the commercially successful device), and therefore this in and of itself establishes a prima facie case of nexus between the commercial success and the merits of the patented invention. Demaco Corp. v. F. Von Langsdorff Licensing Ltd., 851 F.2d 1387 (Fed. Cir. 1988), cert. denied, 488 U.S. 956 (1988).

As set forth in the Zielanski Declaration, Beekley has enjoyed considerable and ever-increasing commercial success in connection with these Light Image markers. Since 1997, Beekley's sales of these markers have been approximately as follows:

Product	Number of Boxes	Number of Markers	Approximate Retail Dollar Value
Light Image A-SPOTS	19,600	2,352,000	$1,038,800
Light Image O-SPOTS	77,347	4,486,126	$4,099,391
Light Image S-SPOTS	48,267	3,317,355	$2,558,151
Totals:	145,214	10,155,481	$7,696,342

Moreover, as further set forth in the Zielanski Declaration and reprinted below, Beekley has enjoyed continually increasing sales per year since introducing these Light Image markers:

Year	Total Number Of Light Image Boxes
1997	16,669
1998	32,974
1999	36,634
2000	42,001
2001 (first quarter only)	8936

(Zielanski Declaration at ¶s 3-5).

As set forth in paragraph 6 of the Zielanski Declaration, these substantial sales equate to a market share of greater than about 50% for the Beekley O-SPOTS® Light Image markers. Accordingly, Beekley's Light Image markers constitute a significant and ever-increasing portion of the overall market for mammographic markers. Moreover, this substantial market share was obtained relatively immediately, i.e., within the first 3-4 years of product introduction. (Zielanski Declaration at ¶s 6 and 8).

Although the fact that Beekley's Light Image markers are coextensive with the claimed invention establishes the requisite nexus between the commercial success and the claimed invention, the Zielanski Declaration further establishes that the claimed features of the invention are the critical factor in motivating medical practitioners to purchase the markers of the invention. As set forth at paragraph 9 of the Zielanski Declaration, many of Beekley's Light Image marker customers previously refused to purchase and use skin markers because conventional radiopaque markers (like those taught by Zinreich et al. and Desena) would block out anatomical detail present in the tissue underlying the marker. Accordingly, these customers only started using skin markers when Beekley's Light Image markers became commercially available, and such customers now regularly use the Light Image markers in their medical practices. (Zielanski Declaration at ¶ 9).

Moreover, prior to introducing the Light Image O-SPOTS and S-SPOTS markers, Beekley had manufactured and sold corresponding radiopaque markers. The only essential difference between these corresponding radiopaque and Light Image markers is that the Light Image markers are made of a material that allows imaging of the anatomical detail present in the tissue such that it is clearly visible through the radiographic shadow projected by the marker, as recited in the independent claims. (Zielanski Declaration at ¶ 3). Since introducing the Light Image markers, Beekley has sold substantially more Light Image markers than corresponding radiopaque markers. For example, in the year 2000, Beekley sold approximately 1.8 million O-SPOTS markers, and of these, approximately 1.3 million were Light Image O-SPOTS markers. (Zielanski Declaration at ¶ 9). Accordingly, the commercial success of the Light Image markers is clearly attributable to the claimed features of the invention.

Moreover, although Beekley is not required to prove that the commercial success is not due to factors other than the claimed invention, this commercial success is clearly not the result of extensive advertising, nor is it the result of aggressive pricing or discounts. Rather, as set forth in the Zielanski Declaration, the Beekley Light Image markers are *more* expensive than substantially all competing markers. In addition, Beekley has initiated very little advertising in connection with the markers of the invention, but rather has marketed the invention almost entirely through product sampling. (Zielanski Declaration at ¶s 7 and 8).

D. Conclusion

It is respectfully submitted that the clear evidence of commercial success, coupled with the reasons set forth above distinguishing the claimed invention from the cited references, indisputably shows that independent claims 20, 36, 46, 55 and 59 are unobvious in view of each of Zinreich et al. and DeSena, for at least these reasons. Because claims 21-35, 37-45, 47-53, 54, 56-58, 60 and 61 each depend from, and therefore include all of the limitations of one of these independent claims, it is respectfully submitted that these dependent claims likewise are unobvious over the prior art references of record for the same reasons as the independent claims, and for reciting additional patentable subject matter.

Accordingly, for the foregoing reasons, reversal of the Final Rejection of Claims 20-61 is warranted and such action is earnestly solicited.

A check in the amount of $160.00 is enclosed for payment of the fee under 37 C.F.R. §1.17(c). No additional fee is believed to be required in connection with

this filing. However, if an additional fee is required, or otherwise if necessary to cover any deficiency in fees already paid, authorization is hereby given to charge our deposit account no. 50-1631.

Respectfully submitted,

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VIII. APPENDIX

Applicant's amendments of October 10, 2000 and April 23, 2001 were entered for the purpose of this appeal. The claims which follow include those amendments.

20. A method of radiographic examination of tissue having anatomical detail present in the tissue, comprising the steps of:

providing a source of x-ray radiation capable of generating radiation suitable for imaging the tissue;

selecting a partially radiolucent, partially radiopaque marker having a radiographic density and thickness which permit the marker to both project a radiographic shadow and transmit sufficient radiation to image anatomical detail present in the tissue when the marker and the tissue are exposed to the x-ray radiation during radiographic examination, wherein the marker comprises at least one of aluminum, rubber, plastic and vinyl, the thickness of the marker is less than about 0.4 inches, and the thickness of the marker is selected based upon the density of the tissue being examined and the energy of the radiation being applied to absorb from about 2% to about 75% of the incident radiation;

positioning the marker between the source of x-ray radiation and the tissue; and

exposing the marker and the tissue to the x-ray radiation, and generating a radiographic image of the tissue having the shadow of the marker superimposed

thereon with the anatomical detail present in the tissue clearly visible through the radiographic shadow projected by the marker.

21. A method of radiographic examination as defined in claim 20, wherein the marker comprises aluminum having a thickness less than about 0.022 inches.

22. A method of radiographic examination as defined in claim 21, wherein the marker comprises aluminum having a thickness of about 0.011 to about 0.022 inches.

23. A method of radiographic examination as defined in claim 20, wherein the marker comprises rubber having a thickness less than about 0.4 inches.

24. A method of radiographic examination as defined in claim 23, wherein the marker comprises rubber having a thickness of about 0.2 to about 0.4 inches.

25. A method of radiographic examination as defined in claim 20, wherein the marker comprises plastic having a thickness less than about 0.2 inches.

26. A method of radiographic examination as defined in claim 25, wherein the marker comprises plastic having a thickness of about 0.1 to about 0.2 inches.

27. A method of radiographic examination as defined in claim 20, wherein the marker comprises plastic and metal and defines a thickness less than about 0.040 inches.

28. A method of radiographic examination as defined in claim 27, wherein the marker comprises plastic and metal and defines a thickness of about 0.015 to about 0.040 inches.

29. A method of radiographic examination as defined in claim 27, wherein the marker comprises plastic impregnated with metal.

30. A method of radiographic examination as defined in claim 20, wherein the marker comprises vinyl having a thickness less than about 1 mm.

31. A method of radiographic examination as defined in claim 30, wherein the marker comprises vinyl having a thickness of about 0.75 mm to about 1 mm

32. A method of radiographic examination as defined in claim 20, wherein the radiographic examination is a mammographic examination and the tissue examined is breast tissue.

33. A method of mammographic examination as defined in claim 32, wherein the energy of the source of radiation is selected to be within the range of about 20kV to about 40kV.

34. A method of radiographic examination as defined in claim 20, wherein the tissue defines a density approximately equal to at least one of a skull, spine and chest, and the energy of the source of radiation is selected to be within the range of about 70kV to about 120kV.

35. A method of mammographic examination as defined in claim 32, wherein the marker is positioned on the patient's breast.

36. A method of radiographic examination of tissue having anatomical detail present in the tissue, comprising the steps of:

providing a source of x-ray radiation having a predetermined energy level capable of generating radiation suitable for imaging a predetermined tissue density;

providing a partially radiolucent, partially radiopaque marker having a radiographic density and thickness which permit the marker to both project a radiographic shadow and transmit sufficient radiation to image anatomical detail present in tissue having the predetermined tissue density when the marker and the tissue are exposed to the predetermined level of x-ray radiation during radiographic examination, said providing step including selecting the density and thickness of the marker based on the predetermined tissue density and the predetermined energy level of the radiation provided to absorb from about 2% to about 75% of the incident radiation;

positioning the marker between the source of x-ray radiation and the tissue having the predetermined tissue density; and

exposing the marker and the tissue to the x-ray radiation at the predetermined energy level, and generating a radiographic image of the tissue having the shadow of the marker superimposed thereon with the anatomical detail present in the tissue clearly visible through the radiographic shadow projected by the marker.

37. A method of radiographic examination as defined in claim 36, wherein the marker is constructed of at least one of aluminum, rubber, plastic and vinyl, and the thickness of the marker is less than about 0.4 inches.

38. A method of radiographic examination as defined in claim 36, wherein the radiographic examination is a mammographic examination, the tissue is breast tissue having a density approximately equal to that of water, the predetermined energy level of the source of x-ray radiation is within the range of about 20kV to about 40kV, and the marker is positioned on a patient's breast.

39. A method of radiographic examination as defined in claim 36, wherein the marker is selected from the group including: (i) a marker comprising rubber having a thickness of less than about 0.4 inches; (ii) a marker comprising plastic having a thickness of less than about 0.2 inches; (iii) a marker comprising vinyl having a thickness of less than about 1 mm; and (iv) a marker comprising aluminum having a thickness of less than about 0.022 inches.

40. A method of radiographic examination as defined in claim 39, wherein the predetermined tissue density is approximately equal to that of water, and the predetermined energy level of the source of x-ray radiation is within the range of about 20kV to about 40kV.

41. A method of radiographic examination as defined in claim 36, further comprising the step of providing a plurality of different markers, each of the different markers defining a respective radiographic density and thickness different than the other markers, and corresponding to a respective tissue density.

42. A method of radiographic examination as defined in claim 41, wherein a first marker defines a first radiographic density approximately equal to the density of water; a second marker defines a second radiographic density approximately equal to the density of the bones of a patient's extremities; and a third marker defines a third radiographic density approximately equal to the density of at least one of a skull, spine or chest of a patient.

43. A method of radiographic examination as defined in claim 42, further comprising the steps of:

(a) positioning the first marker between the source of x-radiation and tissue having a density approximately equal to the density of water, transmitting radiation within the range of about 20kV to about 40kV through the first marker and the tissue, and generating a radiographic image of the tissue having the shadow of the first marker

superimposed thereon with the anatomical detail present in the tissue clearly visible through the radiographic shadow projected by the first marker;

(b) positioning the second marker between the source of x-radiation and tissue having a density approximately equal to the density of the bones of a patient's extremities, transmitting radiation within the range of about 40kV to about 70kV through the second marker and the tissue, and generating a radiographic image of the tissue having the shadow of the second marker superimposed thereon with the anatomical detail present in the tissue clearly visible through the radiographic shadow projected by the second marker; and

(c) positioning the third marker between the source of x-radiation and tissue having a density approximately equal to the density of at least one of a skull, spine and chest of a patient, transmitting radiation within the range of about 70kV to about 120kV through the third marker and the tissue, and generating a radiographic image of the tissue having the shadow of the third marker superimposed thereon with the anatomical detail present in the tissue clearly visible through the radiographic shadow projected by the third marker.

44. A method of radiographic examination as defined in claim 36, further comprising the steps of providing markers having a uniform density throughout each marker, and generating radiographic images of said markers having uniform, translucent appearances without visible irregularities, conflicting striations or granulation obscuring the resolution of the anatomical detail present in the tissue.

45. A method of radiographic examination as defined in claim 36, further comprising the steps of providing a plurality of said markers in predetermined shapes enhancing the information communicated by the markers, including:

(a) a first marker defining the shape of a circle [an arrow];

(b) a second marker defining the shape of a triangle; and

(c) a third marker defining the shape of a straight line [cross;

(d) a fourth marker defining the shape of a circle; and

(e) a fifth marker defining the shape of a straight line].

46. A marker for radiographic examination of tissue having anatomical detail present in the tissue, wherein a source of x-ray radiation is provided for generating radiation at a predetermined energy level suitable for imaging tissue having a predetermined tissue density, the marker is positioned between the source of x-ray radiation and the tissue, and the marker and tissue type are exposed to the x-ray radiation at the predetermined energy level to generate a radiographic image of the tissue having the shadow of the marker superimposed thereon, the marker comprising:

a first outer surface for contacting a patient's skin; a second outer surface located on an opposite side of the marker relative to the first outer surface; and at least one partially radiolucent, partially radiopaque material located therebetween, said at least one partially radiolucent, partially radiopaque material defining a density and thickness based on the predetermined tissue density and the predetermined energy level of the radiation provided which absorbs from about 2% to about 75% of the incident radiation and, in turn, generates a radiographic image of the tissue having

the shadow of the marker superimposed thereon with the anatomical detail present in the tissue clearly visible through the radiographic shadow projected by the marker.

47. A radiographic marker as defined in claim 46, wherein the partially radiopaque, partially radiolucent material is selected from the group including: (i) rubber having a thickness of less than about 0.4 inches; (ii) plastic having a thickness of less than about 0.2 inches; (iii) vinyl having a thickness of less than about 1 mm; and (iv) aluminum having a thickness of less than about 0.022 inches.

48. A radiographic marker as defined in claim 46, wherein the partially radiopaque, partially radiolucent material is selected from the group including: (i) rubber having a thickness within the range of 0.2 to about 0.4 inches; (ii) plastic having a thickness within the range of about 0.1 to about 0.2 inches; (iii) vinyl having a thickness within the range of about 0.75 mm about 1 mm; and (iv) aluminum having a thickness within the range of about 0.011 to about 0.022 inches.

49. A plurality of radiographic markers as defined in claim 46, wherein each of the plurality of markers defines a respective radiographic density and thickness different than the other markers and corresponds to a respective tissue density for imaging tissue having that density, and including (i) a first marker defining a radiographic density approximately equal to the density of water for imaging relatively soft tissue; (ii) a second marker defining a radiographic density

approximately equal to the density of the bones of a patient's extremities for imaging relatively intermediate density tissue; and (iii) a third marker defining a radiographic density approximately equal to the density of at least one of a skull, spine and chest of a patient for imaging relatively dense tissue.

50. A radiographic marker as defined in claim 46, wherein the partially radiopaque, partially radiolucent material includes metal and plastic having an overall thickness of about 0.040 inches.

51. A radiographic marker as defined in claim 50, wherein the partially radiopaque, partially radiolucent material includes metal and plastic having an overall thickness of about 0.015 to about 0.040 inches.

52. A radiographic marker as defined in claim 50, wherein the plastic is impregnated with the metal.

53. A radiographic marker as defined in claim 52, wherein the plastic is impregnated with barium.

54. A method of radiographic examination as defined in claim 45, wherein said step of providing a plurality of said markers in predetermined shapes further includes providing:

(d) a fourth marker defining the shape of cross; and

(e) a fifth marker in the shape of an arrow.

55. A marker for mammographic examination of breast tissue having anatomical detail present in the tissue, wherein a source of x-ray radiation is provided for generating radiation at a predetermined energy level suitable for imaging breast tissue, the marker is positioned between the source of x-ray radiation and the breast tissue, and the marker and breast tissue are exposed to the x-ray radiation at the predetermined energy level to generate a radiographic image of the tissue having the shadow of the marker superimposed thereon, the marker comprising:

a first outer surface for contacting a patient's breast tissue; a second outer surface located on an opposite side of the marker relative to the first outer surface; and means located between the first and second outer surfaces for generating a radiographic image of the tissue having the shadow of the marker superimposed thereon with the anatomical detail present in the tissue clearly visible through the radiographic shadow projected by the marker.

56. A mammography marker as defined in claim 55, wherein said means includes at least one partially radiolucent, partially radiopaque material defining a density and thickness based on the breast tissue density and the predetermined energy level of the radiation provided which absorbs from about 2% to about 75% of the incident radiation.

57. A mammography marker as defined in claim 56, wherein the partially radiopaque, partially radiolucent material is selected from the group including: (i) rubber having a thickness of less than about 0.4 inches; (ii) plastic having a thickness of less than about 0.2 inches; (iii) vinyl having a thickness of less than about 1 mm; and (iv) aluminum having a thickness of less than about 0.022 inches.

58. A mammography marker as defined in claim 57, wherein the plastic is impregnated with the metal.

59. A method of mammographic examination of breast tissue having anatomical detail present in the tissue, comprising the steps of:

providing a source of x-ray radiation having a predetermined energy level capable of generating radiation suitable for imaging breast tissue;

providing a partially radiolucent, partially radiopaque marker having a radiographic density and thickness which permit the marker to both project a radiographic shadow and transmit sufficient radiation to image anatomical detail present in breast tissue when the marker and the tissue are exposed to the predetermined level of x-ray radiation during mammographic examination;

positioning the marker between the source of x-ray radiation and the breast tissue; and

exposing the marker and the tissue to the x-ray radiation at the predetermined energy level, and generating a radiographic image of the tissue having the shadow of the

marker superimposed thereon with the anatomical detail present in the tissue clearly visible through the radiographic shadow projected by the marker.

60. A method of mammographic examination as defined in claim 59, wherein said providing step includes selecting the density and thickness of the marker based on the breast tissue density and the predetermined energy level of the radiation provided to absorb from about 2% to about 75% of the incident radiation.

61. A method of mammographic examination as defined in claim 59, further comprising the steps of adhesively securing the marker to a patient's breast tissue such that the marker is positioned between the source of x-radiation and the breast tissue, transmitting radiation within the range of about 20kV to about 40kV through the marker and the underlying breast tissue, and generating a radiographic image of the tissue having the shadow of the marker superimposed thereon with the anatomical detail present in the tissue clearly visible through the radiographic shadow projected by the marker.